

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARDY DIAGNOSTICS, INC.,)	
)	
Plaintiff, Counter-Defendant)	
)	
v.)	C.A. No. 24-1355 (JDW)
)	
IRHYTHM TECHNOLOGIES, INC.,)	JURY TRIAL DEMANDED
)	
Defendant, Counter-Plaintiff.)	

**DEFENDANT IRHYTHM TECHNOLOGIES, INC.’S ANSWER TO PLAINTIFF
BARDY DIAGNOSTICS, INC.’S AMENDED COUNTERCLAIMS**

Defendant iRhythm Technologies, Inc. (“Defendant” or “iRhythm”), by and through its undersigned counsel, hereby answers the Counterclaims of Bardy Diagnostics, Inc. (“Plaintiff” or “Bardy”) as follows:

I. ANSWER TO BARDY’S AMENDED COUNTERCLAIMS

THE PARTIES¹

1. iRhythm lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 1 of Bardy’s Counterclaims and, on that basis, denies them.

2. iRhythm admits that it was incorporated in the State of Delaware on September 14, 2006. iRhythm admits that its executive offices are located at 699 8th Street, Suite 600, San Francisco, CA 94103. iRhythm denies any remaining allegations in paragraph 2 of Bardy’s Counterclaims.

¹ To the extent that Bardy intends the headings in its Counterclaims to constitute allegations, iRhythm explicitly denies them. The headings in iRhythm’s answer are not responses to the headings in Bardy’s Counterclaims.

NATURE OF THE ACTION

3. iRhythm admits that Bardy purports to allege an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including specifically 35 U.S.C. § 271. iRhythm denies any alleged infringement and further denies that Bardy is entitled to the relief it seeks for any alleged infringement of U.S. Patent Nos. 12,161,473 (the “‘473 patent”), 12,171,562 (the “‘562 patent”), U.S. Patent No. 12,285,261 (the “‘261 patent”), and U.S. Patent No. 12,310,735 (the “‘735 Patent”) (collectively, the “Bardy Asserted Patents”). iRhythm denies any remaining allegations of paragraph 3 of Bardy’s Counterclaims.

4. iRhythm admits that it brought counterclaims alleging patent infringement by Bardy under 35 U.S.C. § 1, *et seq.*, including specifically 35 U.S.C. § 271, of iRhythm’s patents including U.S. Patent Numbers 12,133,734 (the “‘734 patent”), 12,245,859 (the “‘859 patent”), 12,245,860 (the “‘860 patent”), 12,274,554 (the “‘554 patent”), and 12,303,277 (the “‘277 patent”) (collectively, the “iRhythm Asserted Patents”). iRhythm denies any remaining allegations of paragraph 4 of Bardy’s Counterclaims.

JURISDICTION AND VENUE

5. Paragraph 5 of Bardy’s Counterclaims states a legal conclusion to which no response is necessary. To the extent a response is required, iRhythm admits that this Court has subject matter jurisdiction over Bardy’s Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). iRhythm denies any remaining allegations of paragraph 5 of Bardy’s Counterclaims.

6. iRhythm admits that it is incorporated in the State of Delaware. For the purposes of this case only, iRhythm admits that this court has personal jurisdiction over it. iRhythm denies the remaining allegations of paragraph 6 of Bardy’s Counterclaims.

7. The statements set forth in paragraph 7 constitute legal conclusions. To the extent a response is required, iRhythm admits that it is incorporated in the State of Delaware and that

venue is proper in this judicial district under 28 U.S.C. § 1400(b). iRhythm denies any remaining allegations of paragraph 7 of Bardy's Counterclaims.

**COUNT I: DECLARATORY JUDGMENT OF
[ALLEGED] NON-INFRINGEMENT OF U.S. PATENT NO. 12,133,734**

8. iRhythm incorporates by reference its responses to paragraphs 1-7 as if fully set forth herein.

9. iRhythm admits that its first counterclaim alleges that Bardy has infringed and willfully infringed, either literally or under the doctrine of equivalents, the '734 patent by making, using, selling, importing, and/or offering to sell the CAM patch in the United States and that each of these individual activities is an act of infringement under 35 U.S.C. § 271. iRhythm further admits that Bardy has continued to make, use, sell, import, and offer to sell the CAM patch in the United States. iRhythm denies any remaining allegations of paragraph 9 of Bardy's Counterclaims.

10. iRhythm denies the allegations of paragraph 10 of Bardy's Counterclaims.

11. iRhythm admits that claim 1 of the '734 patent recites, in part, "wherein the housing is configured to tilt at an angle relative to the lower adhesive layer in response to movement of the user." The remaining allegations constitute legal conclusions. To the extent a response is required, iRhythm denies the remaining allegations of paragraph 11 of Bardy's Counterclaims.

12. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the infringement of the '734 patent. iRhythm denies the remaining allegations contained in paragraph 12 of Bardy's Counterclaims.

13. iRhythm denies the allegations of paragraph 13 of Bardy's Counterclaims.

14. iRhythm denies the allegations of paragraph 14 of Bardy's Counterclaims.

**COUNT II: DECLARATORY JUDGMENT OF
[ALLEGED] NON-INFRINGEMENT OF U.S. PATENT NO. 12,245,859**

15. iRhythm incorporates by reference its responses to paragraphs 1-14 as if fully set forth herein.

16. iRhythm admits that its second counterclaim alleged that Bardy has infringed and willfully infringed, either literally or under the doctrine of equivalents, the '859 patent by making, using, selling, importing, and/or offering to sell the CAM patch in the United States and that each of these individual activities is an act of infringement under 35 U.S.C. § 271. iRhythm further admits that Bardy has continued to make, use, sell, import, and offer to sell the CAM patch in the United States. iRhythm denies any remaining allegations of paragraph 16 of Bardy's Counterclaims.

17. iRhythm denies the allegations of paragraph 17 of Bardy's Counterclaims.

18. iRhythm admits that claim 1 of the '859 patent recites, in part, "a first spring contact configured to electrically couple a battery to a circuit board assembly housed within the first housing portion" and "wherein at least a portion of the flexible electrode trace is in electrical contact with a second spring contact, and wherein the second spring contact is further configured to electrically couple the flexible electrode trace to the circuit board assembly." The remaining allegations constitute legal conclusions. To the extent a response is required, iRhythm denies the remaining allegations of paragraph 18 of Bardy's Counterclaims.

19. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the infringement of the '859 patent. iRhythm denies the remaining allegations contained in paragraph 19 of Bardy's Counterclaims.

20. iRhythm denies the allegations of paragraph 20 of Bardy's Counterclaims.

21. iRhythm denies the allegations of paragraph 21 of Bardy's Counterclaims.

**COUNT III: DECLARATORY JUDGMENT OF
[ALLEGED] NON-INFRINGEMENT OF U.S. PATENT NO. 12,245,860**

22. iRhythm incorporates by reference its responses to paragraphs 1-21 as if fully set forth herein.

23. iRhythm admits that its third counterclaim alleged that Bardy has infringed and willfully infringed, either literally or under the doctrine of equivalents, the '860 patent by making, using, selling, importing, and/or offering to sell the CAM patch in the United States and that each of these individual activities is an act of infringement under 35 U.S.C. § 271. iRhythm further admits that Bardy has continued to make, use, sell, import, and offer to sell the CAM patch in the United States. iRhythm denies any remaining allegations of paragraph 23 of Bardy's Counterclaims.

24. iRhythm denies the allegations of paragraph 24 of Bardy's Counterclaims.

25. iRhythm admits that claim 1 of the '860 patent recites, in part, "a spring contact configured to electrically couple a battery to a circuit board assembly housed within a first housing portion" and "wherein at least a portion of the flexible electrode is in electrical contact with a second spring contact, and wherein the second spring contact is further configured to electrically couple the flexible electrode trace to the circuit board assembly." The remaining allegations constitute legal conclusions. To the extent a response is required, iRhythm denies the remaining allegations of paragraph 25 of Bardy's Counterclaims.

26. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the infringement of the '860 patent. iRhythm denies the remaining allegations contained in paragraph 26 of Bardy's Counterclaims.

27. iRhythm denies the allegations of paragraph 27 of Bardy's Counterclaims.

28. iRhythm denies the allegations of paragraph 28 of Bardy's Counterclaims.

**COUNT IV: DECLARATORY JUDGMENT OF
[ALLEGED] NON-INFRINGEMENT OF U.S. PATENT NO. 12,274,554**

29. iRhythm incorporates by reference its responses to paragraphs 1-28 as if fully set forth herein.

30. iRhythm admits that its fourth counterclaim alleged that Bardy has infringed and willfully infringed, either literally or under the doctrine of equivalents, the '554 patent by making, using, selling, importing, and/or offering to sell the CAM patch in the United States and that each of these individual activities is an act of infringement under 35 U.S.C. § 271. iRhythm further admits that Bardy has continued to make, use, sell, import, and offer to sell the CAM patch in the United States. iRhythm denies any remaining allegations of paragraph 30 of Bardy's Counterclaims.

31. iRhythm denies the allegations of paragraph 31 of Bardy's Counterclaims.

32. iRhythm admits that claim 1 of the '554 patent recites, in part, that "the flexible layer comprises a polymer upper layer overlying an electrical connection, the electrical connection extending linearly from the physiologic data collection circuit to the electrode when viewed from above the electronic device, the polymer upper layer adhered to a polymer lower layer underlying the electrical connection." The remaining allegations constitute legal conclusions. To the extent a response is required, iRhythm denies the remaining allegations of paragraph 32 of Bardy's Counterclaims.

33. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the infringement of the '554 patent. iRhythm denies the remaining allegations contained in paragraph 33 of Bardy's Counterclaims.

34. iRhythm denies the allegations of paragraph 34 of Bardy's Counterclaims.

35. iRhythm denies the allegations of paragraph 35 of Bardy's Counterclaims.

**COUNT V: DECLARATORY JUDGMENT OF
[ALLEGED] INVALIDITY OF U.S. PATENT NO. 12,133,734**

36. iRhythm incorporates by reference its responses to paragraphs 1-35 as if fully set forth herein.

37. The allegations of paragraph 37 constitute legal conclusions to which no response is required. To the extent a response is required, iRhythm denies the allegations of paragraph 37 of Bardy's Counterclaims.

38. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the validity of the '734 patent. iRhythm denies the remaining allegations contained in paragraph 38 of Bardy's Counterclaims.

39. iRhythm denies the allegations of paragraph 39 of Bardy's Counterclaims.

40. iRhythm denies the allegations of paragraph 40 of Bardy's Counterclaims.

**COUNT VI: DECLARATORY JUDGMENT OF
[ALLEGED] INVALIDITY OF U.S. PATENT NO. 12,245,859**

41. iRhythm incorporates by reference its responses to paragraphs 1-40 as if fully set forth herein.

42. The allegations of paragraph 42 constitute legal conclusions to which no response is required. To the extent a response is required, iRhythm denies the allegations of paragraph 42 of Bardy's Counterclaims.

43. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the validity of the '859 patent. iRhythm denies the remaining allegations contained in paragraph 43 of Bardy's Counterclaims.

44. iRhythm denies the allegations of paragraph 44 of Bardy's Counterclaims.

45. iRhythm denies the allegations of paragraph 45 of Bardy's Counterclaims.

**COUNT VII: DECLARATORY JUDGMENT OF
[ALLEGED] INVALIDITY OF U.S. PATENT NO. 12,245,860**

46. iRhythm incorporates by reference its responses to paragraphs 1-45 as if fully set forth herein.

47. The allegations of paragraph 47 constitute legal conclusions to which no response is required. To the extent a response is required, iRhythm denies the allegations of paragraph 47 of Bardy's Counterclaims.

48. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the validity of the '860 patent. iRhythm denies the remaining allegations contained in paragraph 48 of Bardy's Counterclaims.

49. iRhythm denies the allegations of paragraph 49 of Bardy's Counterclaims.

50. iRhythm denies the allegations of paragraph 50 of Bardy's Counterclaims.

**COUNT VIII: DECLARATORY JUDGMENT OF
[ALLEGED] INVALIDITY OF U.S. PATENT NO. 12,274,554**

51. iRhythm incorporates by reference its responses to paragraphs 1-50 as if fully set forth herein.

52. The allegations of paragraph 52 constitute legal conclusions to which no response is required. To the extent a response is required, iRhythm denies the allegations of paragraph 52 of Bardy's Counterclaims.

53. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the validity of the '554 patent. iRhythm denies the remaining allegations contained in paragraph 53 of Bardy's Counterclaims.

54. iRhythm denies the allegations of paragraph 54 of Bardy's Counterclaims.

55. iRhythm denies the allegations of paragraph 55 of Bardy's Counterclaims.

**COUNT IX: DECLARATORY JUDGMENT OF
[ALLEGED] NON-INFRINGEMENT OF U.S. PATENT NO. 12,303,277**

56. iRhythm incorporates by reference its responses to paragraphs 1-55 as if fully set forth herein.

57. iRhythm admits that its fifth counterclaim alleged that Bardy has infringed and willfully infringed, either literally or under the doctrine of equivalents, the '277 patent by making, using, selling, importing, and/or offering to sell the CAM patch in the United States and that each of these individual activities is an act of infringement under 35 U.S.C. § 271. iRhythm further admits that Bardy has continued to make, use, sell, import, and offer to sell the CAM patch in the United States. iRhythm denies any remaining allegations of paragraph 57 of Bardy's Counterclaims.

58. iRhythm denies the allegations of paragraph 58 of Bardy's Counterclaims.

59. iRhythm admits that claim 1 of the '277 patent recites, in part, "wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode;" and "wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer." The remaining allegations constitute legal conclusions. To the extent a response is required, iRhythm denies the remaining allegations of paragraph 59 of Bardy's Counterclaims.

60. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the infringement of the '277 patent. iRhythm denies the remaining allegations contained in paragraph 60 of Bardy's Counterclaims.

61. iRhythm denies the allegations of paragraph 61 of Bardy's Counterclaims.

62. iRhythm denies the allegations of paragraph 62 of Bardy's Counterclaims.

**COUNT X: DECLARATORY JUDGMENT OF
[ALLEGED] INVALIDITY OF U.S. PATENT NO. 12,303,277**

63. iRhythm incorporates by reference its responses to paragraphs 1-62 as if fully set forth herein.

64. The allegations of paragraph 64 constitute legal conclusions to which no response is required. To the extent a response is required, iRhythm denies the allegations of paragraph 64 of Bardy's Counterclaims.

65. iRhythm admits that a dispute currently exists between iRhythm and Bardy as to the validity of the '277 patent. iRhythm denies the remaining allegations contained in paragraph 65 of Bardy's Counterclaims.

66. iRhythm denies the allegations of paragraph 66 of Bardy's Counterclaims.

67. iRhythm denies the allegations of paragraph 67 of Bardy's Counterclaims.

RELIEF REQUESTED

iRhythm denies that Bardy is entitled to any of the relief requested in its Counterclaims or any relief whatsoever. iRhythm denies all allegations in Bardy's Counterclaims that have not been specifically admitted in paragraphs 1-67 above.

II. AFFIRMATIVE DEFENSES TO BARDY'S COUNTERCLAIMS

iRhythm asserts the following additional defenses to Bardy's Counterclaims. In doing so, iRhythm does not assume any burden of proof on any issue that is Bardy's burden as a matter of law. iRhythm also reserves the right to amend or supplement these defenses as additional facts become known.

FIRST DEFENSE: FAILURE TO STATE A CLAIM

Bardy's Counterclaims fail to allege facts sufficient to state a cause of action upon which relief may be granted.

SECOND DEFENSE: VALIDITY ('734 PATENT)

The claims of the '734 patent comply with all conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable statutory provisions of Title 35 of the United States Code.

THIRD DEFENSE: VALIDITY ('859 PATENT)

The claims of the '859 patent comply with all conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable statutory provisions of Title 35 of the United States Code.

FOURTH DEFENSE: VALIDITY ('860 PATENT)

The claims of the '860 patent comply with all conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable statutory provisions of Title 35 of the United States Code.

FIFTH DEFENSE: INFRINGEMENT ('734 PATENT)

Bardy has infringed and continues to infringe the '734 patent either literally or under the doctrine of equivalents.

SIXTH DEFENSE: INFRINGEMENT ('859 PATENT)

Bardy has infringed and continues to infringe the '859 patent either literally or under the doctrine of equivalents.

SEVENTH DEFENSE: INFRINGEMENT ('860 PATENT)

Bardy has infringed and continues to infringe the '860 patent either literally or under the doctrine of equivalents.

EIGHTH DEFENSE: VALIDITY ('554 PATENT)

The claims of the '554 patent comply with all conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable

statutory provisions of Title 35 of the United States Code.

NINTH DEFENSE: VALIDITY ('277 PATENT)

The claims of the '277 patent comply with all conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or any other applicable statutory provisions of Title 35 of the United States Code.

TENTH DEFENSE: INFRINGEMENT ('554 PATENT)

Bardy has infringed and continues to infringe the '554 patent either literally or under the doctrine of equivalents.

ELEVENTH DEFENSE: INFRINGEMENT ('277 PATENT)

Bardy has infringed and continues to infringe the '277 patent either literally or under the doctrine of equivalents.

RESERVATION OF ADDITIONAL DEFENSES

iRhythm reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional defenses are appropriate.

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/s/ Lucinda C. Cucuzzella

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CERTIFICATE OF SERVICE

I hereby certify that on July 23, 2025, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused to be served copies of the foregoing document on July 23, 2025, upon the following in the manner indicated:

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